

REMARKS

Claims 1-6 are pending in this application. Claims 1 and 4 have been amended. After entry of this Amendment, claims 1-6 will be pending for consideration.

I. Claim Rejections - 35 U.S.C. § 112

Claims 1-6 stand rejected under 35 U.S.C. § 112, second paragraph. The Examiner asserts that claim 1 is vague, indefinite and confusing in the recitation of "wherein the DNA sequence that corresponds to the microorganism's 16S ribosomal RNA is substantially homologous to the sequence as shown in SEQ ID NO:1".

According to the Examiner, the degree of correspondence between DNA and RNA is unclear and the scope of "substantially homologous" cannot be readily determined.

In response, Applicants have amended claim 1. Support for this amendment is found in the specification (page 4, first paragraph), wherein it states that "[t]he term "substantially homologous" used herein refers to homology of 98% or higher in view of, for example, error frequency in nucleotide sequencing of DNA." The DNA sequence in claim 1 is clearly defined as a sequence associated with 16S ribosomal RNA and having homology of 98% or higher with the SEQ ID NO:1. Therefore, in view of this explanation and the above amendment, Applicants respectfully submit that this rejection is now moot.

II. Claim Rejections - 35 U.S.C. §112

Claims 2-3 and 5-6 stand rejected under 35 U.S.C. §112, first paragraph. The Examiner asserts that the invention appears to employ specific mutant strains to obtain certain amounts of canthaxanthin, and that it is not clear if the written description is sufficiently repeatable to avoid the need for a deposit.

In response, Applicants respectfully submit that, as demonstrated in each Example in the specification, mutated canthaxanthin-producing microorganisms can be easily derived from astaxanthin-producing microorganism (e.g. E-396 (FERM BP-4283), A-581-

1(FERM BP-4671)) with a high probability. Therefore, it is clear that the present invention is highly producible and that a person skilled in the art could easily make and/or use the present invention in accordance with the disclosure of the specification.

With regard to the specifically recited strains E-396 and A-581, applicants' attorney points out that these strains have been deposited at The National Institute of Bioscience and Human Technology, Chuo 6 1-1-1 Higashi, Tsukuba, Ibaraki, 305-8566, Japan, which is recognized under the provisions of the Budapest Treaty. Under Rule 803, a depository recognized under the Budapest Treaty meets the requirements noted by the Examiner in the present Office Action. The Accession numbers for E-396 and A-581 are FERM BP-4283 and FERM BP-4671, respectively, as noted above and in the specification at pages 4 and 5.

III. Claim Rejections - 35 U.S.C. § 102 and 35 U.S.C. § 103

Claims 1 and 4 stand rejected under 35 U.S.C. 102 (b) as being clearly anticipated by Tsubokura *et al.* The Examiner asserts that the claims are directed to a process of mutating and culturing a strain such as a mutant of strain E-396 for the production of canthaxanthin. The Examiner further asserts that Tsubokura *et al.* teach a process of mutating and culturing a strain such as E- 396, wherein the mutant strain Y-1071 is cultured for the production of canthaxanthin as claimed. See, *e.g.*, Example 3.

Claims 1-6 stand rejected under 35 U.S.C. 103 (a) as being unpatentable over Tsubokura *et al.* The Examiner asserts that the claims are directed to a process of mutating and culturing a strain such as a mutant of strain E-396 for the production of canthaxanthin in certain amounts. The Examiner further asserts that Tsubokura *et al.* teach a process of mutating and culturing a strain such as E- 396, wherein the mutant strain Y-1071 is cultured for the production of canthaxanthin as claimed. See, *e.g.*, Example 3.

According to the Examiner, the reference differs from the invention as claimed in that the amounts of canthaxanthin and other pigment products are not the same as claimed. The Examiner further contends, however, that the reference teaches methods

of mutation suitable to obtain further mutants and in addition discloses that the manipulation of process conditions, such as concentration of dissolved oxygen affects the results obtained.

The Examiner then concludes that one of ordinary skill in the art would have had a reasonable expectation of success in using the process of Tsubokura *et al.* of mutation and selection and of manipulating oxygen content in the medium to obtain greater yields of canthaxanthin with the mutant obtained.

Applicants traverse these rejections. However, in further response, Applicants respectfully submit that the ratio of canthaxanthin produced from the E-396 is 3.3%-18.5% (Tsubokura *et al.*, Table 4 in Example 3), and the ratio of canthaxanthin produced from the mutant strain Y-1071 is 3.8%-14.5% (Tsubokura *et al.*, Table 7 in Example 3). Therefore, there is almost no change in the canthaxanthin-producing ratio between E-396 and the mutant strain Y-1071.

In contrast, as recited in the claims and described in the Examples, the present invention uses the mutant strain that produces a higher mass percentage of canthaxanthin relative to that produced by the parent strain. This feature, along with the features recited in the dependent claims, is not taught by Tsubokura *et al.* and, contrary to the Examiner's conclusion, this feature is nowhere suggested by Tsubokura *et al.* Therefore, a person skilled in the art would not conceive of the use of, nor be motivated to produce, the mutant strain that produces a higher mass percentage of canthaxanthin relative to that produced by the parent strain. The Examiner arrives at his conclusion of obviousness through hindsight of knowing applicants' invention. This reasoning cannot sustain an obviousness rejection under U.S. law. Accordingly, the present invention is novel and unobvious over Tsubokura *et al.*

CONCLUSION

In light of the above amendments and comments, applicants respectfully request that all rejections and objections be withdrawn and that a timely Notice of Allowance should be issued in this application. Should the Examiner have any questions, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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